

REMARKS

The amendments in the previous case address the Examiner's rejections over the various combinations of the Cajigas, Gonzalez Barberan, Levy, Prescott, et al., Fletcher et al., Merck, Jolly, and Friend et al. references. The new rejection under § 103(a) are based solely on the combination of the new reference Peña Mecho USP 3,234,299, with Cajigas. Applicants assume the reference to Cajigas is to USP 4,289,788.

The difference between the claimed invention and any combination of Peña Mecho and Cajigas is that the present invention is a dry combination of all of the listed components, e.g. the dry bacteria, the non-living yeast, and the protein concentrate, dry, admixed, formulation as claimed, and is, of necessity, both admixed and sealed that way. As noted in Applicant's previous submission, it is important to question whether one of ordinary skill in the art would look to references that do not teach a dry composition to look for a solution to the problem of decreasing bacterial counts in dry powders over a lengthy storage time. Although the Peña Mecho reference discloses bacterial compositions in combination with yeasts and various types of protein species, it is important to recognize that the individual types of bacteria-based compositions disclosed in the Peña Mecho reference are not all dry and that a dry mixture as claimed is never created in Peña Mecho. First, there is a composition described as a "lactic ferment," as well as three distinct microflora compositions that also contain bacterial microorganisms. This latter group is described as the "three equal parts" of the cultured stomach content extracts of the ruminant. These three portions are separated and subjected to various degrees of processing, exposure to vacuum, and dry. However, in each instance, significant moisture content, e.g. moisture above ambient humidity, remain in each part, specifically, 5%, 6%, or 10-12%. These individually-processed parts are then combined with

the “lactic ferment” and the added yeast. Thus, although Peña Mecho discloses a dry bacterial composition, the dry bacterial composition is only present when combined with a separate bacteria-containing composition that has significant moisture content before it is added to the overall composition containing yeast. Therefore, the dry, solid, granular admixture described in the present claims is never produced in the Peña Mecho reference. Moreover, Peña Mecho does not disclose a protein concentrate of the kind disclosed by Applicant as part of a dietary supplement. While the reference discloses addition of some animal source protein “as a biocatheter” in the feed, no significant component of “protein concentrate” as claimed is disclosed by the reference. Thus, no prima facie case under § 103 exists based on the proposed combination of Peña Mecho and Cajigas.

With respect to the specific concentration limitations in claims 38, 39, and 42, the proposed change in concentration contemplated by the Examiner as part of the § 103 rejection actually moves the concentration in the opposite direction to that which would be the natural teaching of the Peña Mecho and/or Cajigas reference. As described in the Peña Mecho specification, the then-existing prior art formulations originally had no microflora from the rumen or reticulum of a ruminant and thus presumably had a lower bacteria concentration, which was then dramatically increased by adding the three bacteria component parts of Peña Mecho before being combined with other feed elements, see e.g. column 6, lines 1-9. Thus, Peña Mecho contains no specific teaching that would instruct one of ordinary skill in the art to lower the amount of bacteria in the mixutre to produce the specific concentration limits claimed in dependent claims 38 and 39. The same is true for claim 42. No conceivable interpretation of Peña Mecho allows a concentration of proteins in the 75%-96% range.

With respect to the availability of a sealed container, it is noted that in the present specification, the use of the sealed container is described as a way to shield admixture and that the individual components have been held in sealed containers to prevent exposure even to atmospheric humidity. In this case, there is no suggestion in Peña Mecho that exposure to any level of humidity is to be avoided. Obviously, because the reference teaches creating specific compositions having 5%, 6%, or 10-12% moisture content, there is no suggestion in the reference to adopt a sealed container for a dry admixture. Thus, even if one of ordinary skill in the art were to consider all possible packaging options, including the sealed container mentioned in passing by the Cajigas reference, there is no express or implied teaching that would lead one of ordinary skill in the art to adopt a sealed container for the mixture of the Peña Mecho reference. Accordingly, there is no basis under the jurisprudence of § 103 to employ a sealed container in the formulation of the present claims.

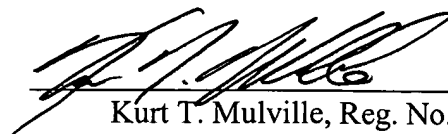
For this reason, Applicants submit that the pending claims are in a position to be allowed.

The Commissioner is authorized to charge \$475.00 to Orrick Herrington & Sutcliffe's Deposit Account for the three-month extension fee. The Commissioner is authorized to charge any fees not covered herewith and to credit any overpayments to Orrick Herrington & Sutcliffe's Deposit Account No. 150665.

Respectfully submitted,

ORRICK, HERRINGTON & SUTCLIFFE LLP

Dated: January 22, 2004 By: _____



Kurt T. Mulville, Reg. No. 37,194

4 Park Plaza, Suite 1600
Irvine, CA 92614-2558
Phone: 949/567-6700, ext.7740
Fax: 949/567-6710